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FOR

EXPANDABLE PENETRATING NEEDLE AND METHOD OF USE

Inventor: Victor Katz

Attorneys: Standley & Gilcrest LLP
Attn.: Eric M. Gayan
495 Metro Place South
Suite 210
Dublin, Ohio 43017-5319
Telephone: (614) 792-5555
Fax: (614) 792-5536
egayan@standleyandgilcrest.com

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BACKGROUND AND SUMMARY OF THE INVENTION

[0001] The present invention relates to an expandable penetrating needle. More specifically, the present invention relates to a needle having a main body that is shaped essentially like a sharply pointed cone when in an unexpanded state, but that opens into a substantially cylindrical shape when expanded. The needle is substantially hollow, such that a second needle or other similar tubing may be passed therethrough. Insertion of a second needle or other tubing into the penetrating needle causes its expansion. The expandable penetrating needle may be used to pierce various materials, such as rubber or plastic. However, the expandable penetrating needle is especially well suited for use in venipuncture procedures, wherein the skin and vein of a patient must be penetrated.

[0002] Various procedures require the non-destructive piercing of a flexible or semi-rigid material, typically in order to gain access to the contents of a container to which the flexible material is affixed. Such materials are commonly formed from a plastic, or more commonly, from a rubber material. For example, rubber stoppers may be used to seal vials or other containers of laboratory chemicals, such as reagents and the like. Access and removal of such chemicals or other materials is typically accomplished by piercing the rubber stopper with a needle, cannula, or other similarly sharp-tipped hollow tool. The desired amount of chemicals may then be drawn into a syringe or

other container. Upon removal of the needle or cannula, the hole produced in the stopper thereby is substantially resealed by the expansion of its rubber composition.

[0003] Another common procedure requiring the non-destructive piercing of a flexible material is the insertion of a needle into the tissue of a patient. One such procedure is commonly referred to as venipuncture, and involves passing a needle through a patients skin and into a vein, whereby access to the patients blood supply is accomplished. Venipuncture may be practiced as a portion of a variety of medical procedures. For example, drug introduction and the drawing of a blood sample (phlebotomy) both employ venipuncture. Various devices may be employed in a typical venipuncture procedure, such as, for example, a hypodermic needle and syringe, a single or multi-sample needle and an evacuated collection tube, and a winged (butterfly) needle that may be connected to an infusion set, a syringe, or an evacuated collection tube. Venipuncture is also practiced when inserting a catheter into a patient's vein. In this case, a needle is used to penetrate the vein and a catheter tube is thereafter inserted into the vein, over the needle, and into the hole in the vein made by the needle.

[0004] Needles come in various shapes and sizes, depending largely on their intended use. For example, needles may be single-ended, such as for use with a syringe, or double-ended, such as for use with an evacuated collection tube. Needles generally consist of a shaft that is inserted into the patient, and a hub for attachment to a syringe, collection tube, or other device. The penetrating end of the needle is typically beveled, with the leading edge

of the bevel forming the point of the needle. Double-ended needles typically have a bevel and point at both ends. The point is typically made as sharp as possible to provide for penetration of a patient's skin and vein (and the rubber stopper of a collection tube in the case of double-ended needles). Needles are also generally hollow to allow for the delivery of fluids or to allow for the withdrawal of an amount of a patient's blood. The passageway that runs through the length of the needle is commonly referred to as the lumen. The diameter of the lumen determines the gauge, or size, of the needle. In addition to their use in venipuncture procedures, such needles may also be used to pierce other flexible materials, as described above.

[0005] The use of such needles is not without problems, however - whether they are used to pierce flexible materials, such as plastic and rubber, or in venipuncture procedures. In order to properly withdraw or inject fluids through a needle, the lumen must be of adequate diameter. Adequate lumen diameter is based, at least somewhat, on the type and viscosity of the material to be passed through the needle. Additionally, a needle will encounter at least some resistance during piercing of a patient's skin, a rubber stopper, or another material to be penetrated. As such, the needle must have sufficient strength and rigidity to prevent it from bending or breaking during insertion. Thus, in addition to the diameter of the lumen, the needle must also have a wall thickness sufficient to impart the necessary rigidity thereto. This wall thickness contributes to the overall diameter of the needle, which diameter must pass through the material to be penetrated.

[0006] Obviously, a needle of greater diameter will create a larger opening in the material it penetrates. Therefore, it is typically desired, particularly in venipuncture, to use the smallest needle possible. The use of a smaller needle will encounter less resistance from a patient's skin and vein (or another material to be penetrated), thereby generally producing less pain and resulting in less bleeding. However, the minimum diameter of a needle used in venipuncture is limited. For example, when dispensing intravenous drugs, the needle must be able to adequately pass the material into the patients vein. In a catheter procedure, the needle must be large enough to create a hole of sufficient size to accept the catheter. And, in phlebotomy, a lumen of too small a diameter can cause damage to red blood cells, leading to an unusable blood sample.

[0007] The bevel common to typical needles is intended to make insertion (penetration) of the needle easier. The bevel allows the diameter of the needle to be inserted incrementally - as opposed to the instantaneous insertion of the needle's diameter that would occur with a blunt (squared off) tip. The use of a bevel also has drawbacks, however. For example, it is known to be somewhat difficult to produce a bevel on needles, especially those of small diameter (gauge), while simultaneously maintaining a sharp point and a clean lumen opening. Also, while the bevel allows for incremental insertion of the needle diameter, it also requires that a greater length of needle be inserted before materials may be withdrawn or injected therethrough. The bevel also imparts a larger surface area to the cutting portion of the needle.

[0008] Thus, use of typical, known needles, can be problematic for a number of reasons. For example, when using such needles to penetrate rubber stoppers or similar other closures, the sharpened bevel of the needle often cuts or otherwise abrades away portions of the closure material. Therefore, holes are eventually formed through the closure that cannot be closed by the expansion of its composition. The closure material may also enter into and clog the needle during insertion. When used in venipuncture, such needles tend to cut a substantial hole into the patient's skin and vein. The greater the gauge of the needle, the larger the hole, and the more pain a patient must endure. Additionally, such needles may be very difficult to use properly on a patient with small, collapsed, or "rolling" veins. In such cases, it is easily possible to pass the tip of the needle through the entire vein, or to completely miss the vein.

[0009] The expandable penetrating needle of the present invention overcomes the aforementioned shortcomings of typical, known needles. In comparison to typical needles, which require that the full diameter of the needle cut through the material to be penetrated (such as the skin and vein of a patient), the expandable penetrating needle of the present invention is designed to produce a smaller initial entryway. Thus, penetration of a subject material by the expandable penetrating needle of the present invention is less invasive than penetration by typical needles.

[0010] In order to produce a minimal entryway through the material to be penetrated, the expandable penetrating needle of the present invention is preferably designed to have a substantially conical shape when in an

unexpanded state. More specifically, the expandable penetrating needle has a shaft that is formed into a segmented cone having a sharp point. The shaft may be perforated, scored, or possess weakened sections, for example, that divide the cone into a plurality of substantially triangular sections. The base of the conical shaft may be attached to a variety of hubs or other similar attachment structures. For example, when employed in the medical field, the expandable penetrating needle may be designed for attachment to a hypodermic syringe, an evacuated collection tube holder, a butterfly infusion system, or a catheter insertion apparatus. A multitude of other configurations are also possible.

[0011] The segmented design of the expandable penetrating needle shaft allows it to expand upon insertion of another device. For example, a section of tubing, such as a second needle or catheter may be inserted into the hub of the expandable penetrating needle. As the second needle or section of tubing is moved toward the tip of the expandable penetrating needle, the individual segments of the conical shaft are forced to separate and expand. Expansion of the segments causes a stretching of the penetrated material surrounding the outside of the expandable penetrating needle shaft, thereby allowing the initially created entryway to be enlarged, and the second needle or tubing to pass therethrough. Consequently, it can be understood that the expandable penetrating needle of the present invention can be used to permit the substantially less invasive insertion of a device of considerably greater diameter than the entryway initially created by the needle. Because the expandable penetrating needle produces an enlarged entryway by gradual

expansion, as opposed to cutting, penetration of a material can be achieved with less destructive effect on the penetrated material and, in the case of venipuncture, with less pain experienced by the patient.

[0012] As discussed above, an expandable penetrating needle of the present invention may have a plurality of uses, and may be connected to a variety of other devices. A better understanding of the expandable penetrating needle of the present invention can be gained by reference to the following detailed description of certain exemplary embodiments thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

[0013] In addition to the features mentioned above, other aspects of the present invention will be readily apparent from the following descriptions of the drawings and exemplary embodiments, wherein like reference numerals across the several views refer to identical or equivalent features, and wherein:

Figure 1a is an enlarged view illustrating a known type of needle, commonly referred to as a hypodermic needle;

Figure 1b is an enlarged view illustrating a similar, known needle, and its use in a catheter assembly;

Figure 2a depicts a venipuncture procedure, wherein a typical hypodermic needle has been inserted into a normal vein of a patient;

Figure 2b depicts a venipuncture procedure, wherein a typical hypodermic needle has been inserted into a small, or collapsed vein of a patient;

Figure 3a is an enlarged view, in partial cross-section, showing one embodiment of an expandable penetrating needle of the present invention in an unexpanded state;

Figure 3b shows the expandable penetrating needle of Figure 3a in an expanded state;

Figure 4a is an enlarged view showing another embodiment of an expandable penetrating needle of the present invention in an unexpanded state;

Figure 4b shows the expandable penetrating needle of Figure 4a in an expanded state;

Figure 5a is an enlarged cross-sectional view of the expandable penetrating needle of Figure 4a;

Figure 5b is an enlarged cross-sectional view, showing a second needle partially inserted into the expandable penetrating needle of Figure 5a;

Figure 5c is an enlarged, partial cut-away view, showing the needle assembly of Figure 5b with substantially full insertion of the second needle into the expandable penetrating needle;

Figure 6a depicts a venipuncture procedure, wherein an expandable penetrating needle of the present invention has been inserted into a small, or collapsed vein of a patient, to facilitate the subsequent insertion of a typical hypodermic needle; and

Figure 6b shows the arrangement of Figure 6a, with the hypodermic needle fully inserted through the expandable penetrating needle and into the patient's vein.

DETAILED DESCRIPTION OF THE EXEMPLARY EMBODIMENT(S)

[0014] The expandable penetrating needle of the present invention is designed to be used in a variety of applications, including those in which typical needles are currently employed. A typical hypodermic needle **5** can be observed by reference to Figure 1a. The hypodermic needle **5** can be seen to have a shaft **10** that is attached at a first end to a hub **15**. The hub **15** is provided to attach or connect the needle **5** to another device, such as a syringe or evacuated collection tube holder, for example. The second end of the shaft **10** is provided with a bevel **20** that forms a point **25** at the tip of the needle **5**. The bevel **20** acts as a cutting edge to allow the shaft **10** of the needle **5** to pass through a material to be penetrated. The hollow interior of the needle is generally referred to as the lumen **30**. The diameter of the lumen **30** determines the gauge, or size, of the needle.

[0015] Other types of needles also exist. For example, double-ended needles, with each end having a bevel, are produced for use with evacuated collection tubes/holders. Such devices are commonly used during phlebotomy. Other needles may be used to provide an entryway, or pilot hole, for the insertion of another device. For example, in the medical field, needles are typically used to create an entryway into a patient's vein for the insertion of a catheter. A portion of such an assembly **35** is depicted in Figure 1b. As can be seen from this portion of the catheter assembly **35**, a penetrating needle **40** is located interior to a section of hollow catheter tubing **50**. It is also possible for the catheter tubing to reside inside the lumen **45** of the needle, although such an arrangement is generally less common. In such

an assembly, the needle **40** is first inserted through a patient's skin and into a vein. Once the needle is secured, the catheter tubing **50** is passed over the needle **40**, and inserted into the vein through the hole therein made by the needle. As the catheter tubing **50** is generally of considerably larger diameter than the needle **40**, the leading end of the catheter tubing may be beveled or otherwise designed to facilitate its entry into the vein. However, even with such treatment, forcing the catheter into the vein will generally cause discomfort to the patient, and may be harmful to the vein and other tissue of the patient through which it passes. Once the catheter tubing **50** is inserted, provision is generally made for removal of the needle **40**.

[0016] Use of a hypodermic needle, like that shown in Figure 1a, can be seen by reference to Figures 2a and 2b. In Figure 2a, the hypodermic needle **5** is shown attached to a syringe **55**. The hypodermic needle **5** has been inserted into the arm **60** of a patient, whereby the needle has penetrated both the skin **65** and a vein **70** of the patient. The needle **5** and syringe **55** are shown to be oriented at a slight angle with respect to horizontal (and the patient's arm), which angle is typically about 15°. As can be observed from Figure 2a, and the following example, an entryway is created through the tissue of the patient's arm by the needle **5**, the angle of entry and beveled cutting edge **20** of which can increase the size of the entryway beyond that of the needle diameter. In this particular example, the needle **5** has been inserted into a substantially normal vein **70** (i.e., the vein is of normal size and is not collapsed).

[0017] The hypodermic needle **5** and syringe **55** of Figure 2a are again shown inserted into the arm **75** of a patient in Figure 2b. Again, the needle **5** and syringe **55** are shown to be oriented at a slight angle with respect to horizontal, and the needle has penetrated through the patient's skin **80** and into a vein **85**. However, in this example the vein **85** is shown to be collapsed, such as may occur from, for example, repeated injection (needle penetration) of the same site. A similar problem may occur when performing venipuncture on a patient with small veins, such as a child or an elderly person. In either case, the vein generally has a significantly reduced diameter. As such, it may be exceedingly difficult, if not impossible, to insert the needle **5** into the vein without at least the tip **25** of the needle also penetrating partially or fully through both walls thereof. Further, insertion of the needle **5** to a point wherein less than the whole of the lumen **30** resides within the vein can cause blood loss and an incomplete blood draw or injection.

[0018] As can be understood from the above examples, when using penetrating needles, it is desirable to minimize the size of the entryway that must be cut through the material to be penetrated. Such is true whether the needle is used to pierce an inanimate object, such as a rubber or cork stopper, or the tissue of a living patient. In either case, minimizing the size of the cut entryway reduces damage to the material to be penetrated and allows the entryway to be more easily resealed after needle withdrawal. Additionally, as expressly shown in the example of Figure 2b, it is also desirable to minimize the size (diameter and length) of such a needle when it is utilized to perform venipuncture on a collapsed, small, or rolling vein.

[0019] The expandable penetrating needle of the present invention minimizes or eliminates many of the disadvantages associated with the use of typical needles. One embodiment of an expandable penetrating needle **100** of the present invention can be observed in Figure 3a. While the embodiment of the expandable penetrating needle shown in Figure 3a, as well as the other exemplary embodiments depicted in the remaining drawing figures will be described specifically with respect to their use in venipuncture, it should be realized that such needles could also be used in a variety of other areas, such as has been briefly discussed above. The expandable penetrating needle **100** of Figure 3a is shown in an unexpanded condition. The expandable penetrating needle **100** can be seen to have a shaft **105** of substantially conical shape. The distal end **110** of the shaft is formed into a sharp point (tip) **115** when the needle **100** is in an unexpanded state, while the proximal end (base) **120** of the shaft is attached to a hub **125**. It is also contemplated that the base **125** of the needle shaft **105** could form the hub **125**. The hub **125** has a forward portion **130** that is attached to the base **120** of the needle shaft **105**, and an open, receiving end **135** opposite thereof. In this particular embodiment, the hub **125** is merely provided to be grasped by a user of the expandable penetrating needle **100** and to receive a section of tubing **160**, such as catheter or intravenous tubing, that will eventually be passed through the needle. Thus, in this particular embodiment, it is not required that the hub **125** be of a specific shape or size.

[0020] When the expandable penetrating needle **100** will be used for phlebotomy, it is preferred that at least the forward portion **130** of the hub **125**

be transparent, or otherwise allow a user of the needle to view a flow of blood from the patient's vein. In this manner, the phlebotomist is able to determine with certainty that the expandable penetrating needle **100** has been adequately inserted into the vein. As will be described in more detail below, the shaft **105** of the expandable penetrating needle **100** may also be modified to facilitate this process.

[0021] The shaft **105** of the expandable penetrating needle **100** is shown to be divided into a plurality of segments **140**, **145**, **150**. In this particular embodiment the shaft is divided into three segments **140**, **145**, **150**, but a fewer or greater number of segments are also possible. The segments **140**, **145**, **150** may be produced by cutting or scoring the shaft, for example. If the expandable penetrating needle **100** is of molded construction, it is also anticipated that the segments **140**, **145**, **150** may be produced by providing minute areas of weakened (thinner) material therebetween. The cuts, score lines, or other means of segmenting the shaft **105** may run through the tip **115** or, alternatively, may stop slightly short of the tip to help ensure that the segments are maintained in a tightly abutting relationship while the expandable penetrating needle **100** is in an unexpanded state.

[0022] As shown in Figure 3a, it is anticipated that the tubing **160** may be partially inserted into the hub **125** of the expandable penetrating needle **100** prior to insertion of the expandable penetrating needle into a patient. For example, the expandable penetrating needle **100** and tubing **160** may be provided as a pre-assembled kit, or the components may be supplied separately and assembled prior to use. Preferably, the fit of the outer

diameter of the tubing **160** and the inner diameter of the hub **125** or the base **120** of the needle shaft **105**, depending on needle construction, provides a substantial seal and also prevents inadvertent movement of the tubing toward the tip **115** of the expandable penetrating needle **100**. Other means of tubing retention may also be employed. For example, it is contemplated that a threaded collar (not shown) may be provided at the open end **135** of the hub **125** to engage a like-threaded portion (not shown) of tubing. In this embodiment, rotation of the collar in a first direction controllably and incrementally forces the tubing into the needle, while rotation of the collar in an opposite direction withdraws the tubing from the needle. The threaded portion of the tubing may be integral thereto or, alternatively, may be applied to the tubing, such as in the form of an adhesively attachable section.

[0023] Once the needle tip **115** has been properly inserted into a patient's vein, the tubing **160** may be pushed through the needle shaft **105**. The expandable penetrating needle **100** may be held in place by the user during this operation but, preferably, the needle is secured to the patient, such as with tape or the like. As the tubing **160** is pushed into the needle, the segments **140**, **145**, **150** are forced to progressively separate, causing the outside diameter of the needle shaft **105** to gradually increase, and thereby slowly stretching the initial entryway produced in the vein by the needle tip **115**. As the tubing approaches the now open distal end **110** of the expandable penetrating needle **100**, the needle shaft **105** becomes substantially cylindrical in shape, with its inner diameter typically, but not essentially, similar in dimension to the outside diameter of the tubing **160**. A

mark or similar indicator may be provided on the tubing **160** to alert the user when the distal end thereof has reached the distal end **110** of the needle shaft **105**.

[0024] Once the tubing **160** has been properly inserted into the vein, the user has the option of retracting the expandable penetrating needle **100** from the patient. For example, if the tubing **160** will be used only for a short-term procedure, the user may simply leave the expandable penetrating needle **100** in its inserted position, whereafter it may be withdrawn from the patient along with the tubing. However, if the tubing **160** will be used for a long-term procedure, the user may wish to remove the expandable penetrating needle **100** from the patient and allow only the tubing to remain in the vein. The expanded inner diameter of the needle shaft **105** allows the expandable penetrating needle **100** to be retracted from the patient and moved to a position along the tubing **160** that is safely removed from the patient and/or contact by the user or others. The retracted expandable penetrating needle **100** may be affixed to the tubing **160** by a number of means, such as, for example, a piece of tape. However, it is contemplated that the hub **125** of the expandable penetrating needle **100** may also have an optional retention mechanism **165**, such as the spring-loaded hook shown attached thereto. In this embodiment, the hook **165** is designed to mate with a corresponding connector **170** that is affixed to the tubing **160** at a location away from the patient. As with the expandable penetrating needle **100**, the connector **170** may come pre-installed to the tubing **160**, or may be installed to the tubing by the user prior to installation of the expandable penetrating needle. Preferably,

the connector **170** is designed to be moveable along the length of the tubing **160**, but to also firmly resist inadvertent movement. Such may be accomplished, for example, by carefully controlling the fit of the connector inner diameter to the outer diameter of the tubing **160**, or by forming at least the inner diameter of the connector **170** from a material that firmly but releasably grips the tubing. Such constructions are known and need not be discussed in detail herein.

[0025] An alternate embodiment of an expandable penetrating needle **200** of the present invention in an unexpanded and expanded state is shown in Figures 4a and 4b, respectively. This embodiment of the expandable penetrating needle **200** is similar in design to the embodiment **100** shown in Figures 3a-3b. Like the embodiment of Figures 3a-3b, the expandable penetrating needle **200** can be seen to have a segmented shaft **205** of substantially conical shape with a distal end **210** thereof formed into a sharp point (tip) **215**. The proximal end (base) **220** of the shaft **205** is attached to a specialized hub **225**. The hub **225** has a forward portion **230** that is attached to the base **220** of the needle shaft **205**, and an open, receiving end **235** opposite thereof. In this particular embodiment of the expandable penetrating needle **200**, the hub **225** is specifically designed to mate with the hub of another needle, such as, for example, a hypodermic needle, or a double-ended needle. In this manner, the expandable penetrating needle **200** can be used in conjunction with another needle during venipuncture to more easily penetrate a patient's skin and vein. A hypodermic needle attached to a syringe or a double-ended needle attached to an evacuated collection

tube/holder, for example, may thereafter be inserted through the expandable penetrating needle **200**.

[0026] The expandable penetrating needle **200** depicted in Figures 4a-4b can be seen in cross-section in Figures 5a-5c. As shown in Figure 5a, the base **220** of the needle shaft **205** may be somewhat elongated to help in guiding the device, in this case the needle, that will be passed therethrough. In this particular embodiment of the expandable penetrating needle **200**, the needle shaft **205** and hub **225** are of two-piece construction. Thus, the base **220** of the needle shaft **205** is shown to reside within a forward portion **230** of the hub **225**. It is also contemplated that the forward portion **230** of the hub **225** could reside within the base **220** of the needle shaft **205**. It is also possible that the expandable penetrating needle **200** could be of one piece construction, wherein the base **220** of the needle shaft **205** and the forward portion **230** of the hub **225** could have substantially the same inside diameter.

[0027] Like the shaft **105** of the expanding penetrating needle **100** shown in Figures 3a-3b, the shaft **205** of the expandable penetrating needle **200** is divided into three segments **240**, **245**, **250**. The shaft **205** could also be divided into a fewer or greater number of segments. The segments **240**, **245**, **250** may be produced by cutting or scoring the shaft, for example. If the expandable penetrating needle **200** is of molded construction, it is also anticipated that the segments **240**, **245**, **250** may be produced by providing minute areas of weakened (thinner) material therebetween. The cuts, score lines, or other means of segmenting the shaft **205** may run through the tip **215** or, alternatively, may stop slightly short of the tip to help ensure that the

segments **240**, **245**, **250** are maintained in a tightly abutting relationship while the expandable penetrating needle **200** is in an unexpanded state.

[0028] As shown in Figures 5a-5b, it is also possible that the hub **225** may contain a seal **260**. The seal **260** is provided primarily for use in phlebotomy applications, to help prevent any of the initial flow of blood that occurs after insertion of the tip **215** of the expandable penetrating needle **200** into a patient's vein from exiting the open end **235** of the hub **225**. The design of the seal **260** may depend on the type of second needle **265** to be passed through the expandable penetrating needle **200**. For example, if a blunt-ended second needle is to be used, the seal may be substantially a grommet, wherein a predefined (but substantially sealed) passageway is located therethrough. If the second needle has a beveled end, it may be possible to employ a solid seal **260**, wherein the second needle simply punctures the seal upon its insertion into the expandable penetrating needle **200**.

[0029] As can be best observed by specific reference to Figure 5b, when the second needle **265** is initially inserted into the expandable penetrating needle **200**, it may be guided by the inside diameter of the hub **225**, or in this particular case, the inside diameter of the base **220** of the needle shaft **205**. The length of the guiding section may vary. It is also possible that the outside diameter of the second needle **265** may be smaller than the inside diameter of the hub **225** or base **220** of the needle shaft **205**, in which case the second needle may not make contact with the expandable penetrating needle **200** until the second needle reaches the conical (tapered) portion of the needle shaft **205**. In any event, as the second needle **265** is inserted further into the

expandable penetrating needle **200**, the shaft **205** thereof is caused to expand by a separation of the segments **240**, **245**, **250**. The expandable penetrating needle **200** is shown in an expanded state in Figure 5c.

[0030] As shown in Figure 5c, this particular embodiment of the expandable penetrating needle **200** is designed to mate with, or engage, a hub **270** of the second needle **265**. Further, in this particular embodiment, full insertion of the second needle **265** (as shown) into the expandable penetrating needle **200** is indicated by full insertion of the hub **270** of the second needle **265** into the hub **225** of the expandable penetrating needle **200**. In this case, when the second hub **270** is fully inserted into the expandable penetrating needle hub **225**, the tip **275** of the second needle **265** is substantially aligned with the distal end **210** of the expandable penetrating needle shaft **205**. At full insertion, it is also possible that the tip **275** of the second needle **265** may reside slightly within the expandable penetrating needle shaft **205**, or protrude slightly therefrom. However, it is preferred that the tip **275** the second needle **265** not be allowed to protrude too far from the distal end **210** of the expandable penetrating needle shaft **205**, as it may penetrate through the bottom wall of the vein. In other embodiments, the hub **270** of the second needle **265** may not be inserted into the hub **225** of the expandable penetrating needle **200**. For example, the distal end of the hub **270** of the second needle **265** may simply abut the open end **235** of the expandable penetrating needle **200**. Alternatively, the hubs **225**, **270** may not make contact due to, for example, the length of the second needle **265**. In this case, it is preferable that the second needle **265** be marked to indicate

the point of insertion wherein the tip **275** thereof will exit the open distal end **210** of the expandable penetrating needle shaft **205**.

[0031] As mentioned above with respect to the embodiment of Figures 3a-3b, when used for phlebotomy, it is preferred that at least the forward portion **230** of the hub **225** be transparent, or otherwise allow a user of the expandable penetrating needle **200** to view a flow of blood from the patient's vein. In this manner, the phlebotomist is able to determine with certainty that the expandable penetrating needle **200** has been adequately inserted into the vein. As is best observed in Figures 4a-4b, the shaft **205** of the expandable penetrating needle **200** has also been modified to facilitate this process. More specifically, in this embodiment of the expandable penetrating needle, arcuate sections of the needle shaft segments **240**, **245**, **250** have been removed along the abutting edges **255** (i.e., along the score lines, cut lines, etc., that separate the segments) thereof. Thus, small elliptical-shaped apertures **280** are formed through the needle shaft **205** to allow a small amount of blood to flow into the interior of the expandable penetrating needle **200** while it is still in an unexpanded state. Preferably, the apertures **280** are located toward the tip **215** of the needle shaft **205** so that the initial blood flow may be established with only a minimal insertion of the needle tip into the patient's vein. It is further contemplated that more than one aperture like that shown may be located between the segments, or that one or more apertures of other shape and size may be located between the segments **240**, **245**, **250** of the needle shaft **200**. Alternatively, a single aperture, or multiple apertures may

be located wholly in each segment **240**, **245**, **250** of the needle shaft **205**, as opposed to along the abutting edges **255** thereof.

[0032] The expandable penetrating needle **200** of Figures 4a-4b and 5a-5c is shown in Figures 6a-6b during its use in a venipuncture procedure. In this example, the expandable penetrating needle **200** is used in conjunction with the hypodermic needle **5** and syringe **55** of Figures 2a-2b, although it should be realized that the expandable penetrating needle could be configured to work with virtually any venipuncture device. In the example of Figures 6a-6b, the hypodermic needle **5** and syringe **55** may be used, for example, to introduce an intravenous drug to the patient, or to obtain a blood sample.

[0033] In Figure 6a, the expandable penetrating needle **200** has been inserted into the arm **285** of a patient, whereby the shaft **205** of the expandable penetrating needle has penetrated the patient's skin **290** and the tip **215** of the expandable penetrating needle has penetrated a vein **295** of the patient. In this example, the vein **295** is shown to be collapsed or of small size in order to demonstrate how an expandable penetrating needle of the present invention can facilitate entry thereto more easily than a typical needle. As can be seen, the expandable penetrating needle **200** is oriented at a slight angle with respect to horizontal (and the patient's arm). However, unlike with a typical needle, it should be understood that the conical shape of the expandable penetrating needle **200** may also allow an entry angle (not shown) into the patient's arm that is more vertical.

[0034] As can be observed from Figure 6a, the tip **215** of the expandable penetrating needle **200** creates an initial entryway into the vein **295** of the

patient. However, this initial entryway is of much smaller diameter than would be created by the cutting action of a typical beveled needle. Preferably, apertures **280** or other similar features in the needle shaft **205** allow an initial blood flow to be established, thereby indicating to the user thereof that proper entry of the expandable penetrating needle **200** into the vein **295** has been made. Once the expandable penetrating needle **200** has been properly inserted into the vein **295**, it is preferably, but not necessarily, secured to the patient, such as with a piece of tape.

[0035] Once proper insertion of the expandable penetrating needle **200** into the vein has been established, the hypodermic needle **5** can be inserted therethrough. Progressive insertion of the hypodermic needle **5** into the expandable penetrating needle **200** causes a gradual expansion of the expandable penetrating needle shaft **205**, as well as a gentle expansion of the initial entryway created in the vein **295**. As can be seen in Figure 6b, once the hypodermic needle **5** is substantially fully inserted into the expandable penetrating needle **200**, the expandable penetrating needle shaft **205** becomes substantially fully open (expanded). Thus, the initial entryway in the vein **295** is stretched sufficiently to allow insertion of the larger diameter hypodermic needle **5**, without forcing the hypodermic needle into the vein or requiring any additional cutting thereof. As can be seen in Figure 6b, the expanding action of the needle shaft **205** acts to open up the previously collapsed section of the vein **295**, thereby permitting access by the hypodermic needle **5** without fully penetrating or otherwise causing additional damage to the vein.

[0036] As a byproduct of the design of the expandable penetrating needle of the present invention, the expandable penetrating needle may be provided with a self-blunting feature. For example, in the embodiment shown in Figures 3a-3b, extension of the tubing **160** past the distal end **110** of the needle shaft **105** effectively blunts the end of the expandable penetrating needle **100**. As the expandable penetrating needle **100** may be moved along the tubing **160** in a direction away from the patient after insertion of the tubing, or may otherwise be removed from the patient along with the tubing, accidental needle sticks can be prevented. Similarly, in the embodiment of the expandable penetrating needle **200** illustrated in Figures 4a-4b and 5a-5c, a blunt-ended needle may be substituted for the beveled second needle **265** shown. Consequently, insertion of a blunt-ended second needle to a point wherein its blunt end extends slightly beyond the end **210** of the shaft **205** of the expandable penetrating needle **200**, acts as a safety device (guard) to prevent accidental needle sticks from the sharp points **215** thereof. Thus, in certain embodiments, the expandable penetrating needle of the present invention may be a part of a self-blunting apparatus.

[0037] While certain exemplary embodiments of the present invention are described in detail above, it should be realized that a pluarality of modifications are possible within the scope of the invention.. For example, as mentioned above, the expandable penetrating needle of the present invention can be configured to connect to substantially any venipuncture device available. The expandable penetrating needle may be manufactured from virtually any material that provides the necessary strength and allows for the

segmentation thereof. A multitude of different connectors, guards, etc., may be provided for storing and/or covering the expandable penetrating needle after its initial use. Further, the expandable penetrating needle of the present invention is not limited to use in venipuncture procedures, or to medical procedures in general but, rather, may be employed anywhere a needle would typically be used to pierce or penetrate a material. Therefore, the present invention is not to be considered limited by the above disclosure of exemplary embodiments, and modifications are possible without departing from the spirit of the invention as evidenced by the following claims: